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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,300	07/05/2001	Achim Berthold	R00282US (#90568)	8251

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/02/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,300

Applicant(s)

BERTHOLD, ACHIM

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt of Request for Continued Examination, Amendment C, and Information Disclosure Statement received on April 7, 2003 is acknowledged. Claims 15-25 are included in the prosecution of this application.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on Amendment C.

Specification

A Brief Description of the Drawing(s) is missing in applicant's specification and is required. See MPEP § 608.01(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 15 and 17 recite a transdermal containing three polymer layers with different glass transition temperatures. The applicant recites the first layer as a temperature of Tg1, the second as a temperature of Tg2, and the third as a temperature of Tg1. The applicant further recites that Tg1 in the first and third layer may have same or different temperatures, which is unclear. If the third layer can have a

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different temperature than Tg1, it should be denoted Tg3 since it cannot be Tg1 since Tg1 defines the first layer's temperature. Further clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al (5,151,271) by itself or in view of Ercillo et al (6,416,858).

Otsuka et al teaches a pressure sensitive adhering composite medicinal preparation. The composite comprises at least two layers, namely at least one macromolecular layer and polymer layer. The polymer layer contains a polymer or copolymer that has a glass transition temperature (Tg) of not lower than -50 degrees Celsius, preferably -45 to 75. This allows an increased degree of diffusion therein of the drug and adjuvant but also does not deteriorate the physical strength. See column 2.

The macromolecular layer functions to secure the preparation to the skin, be compatible

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with the drug and adjuvant, and allow release of the drug and adjuvant. This layer has a Tg of -70 to -10 degrees Celsius. This temperature allows increased shape holding property, does not cause skin irritation, and does not leave a residue when peeled off. See column 3, lines 1-25. Otsuka teaches a release liner. See examples.

Although Otsuka suggest more than three polymer layers, the reference does not exemplify the third layer or a protective layer.

Ercillo et al teach a multi-layer pressure sensitive adhesive construction. The multi-layer construction contains a facestock (protective layer), a first adhesive layer that has one Tg, the second adhesive layer has a Tg of 10 to 50 degrees lower than the first layer, and a release liner. See Figure 2. Ercillo teaches that the degree of tack possessed by a particular adhesive layer is largely dependent on the glass temperature of the layer. If the Tg is too high the composition fails to act as an adhesive. If the Tg is too low than the adhesive composition will flow too readily, which diminishes converting performance. Ercillo teaches several different embodiments switching the layers with the high Tg and the low Tg to balance improved converting and adherent properties of the composite. See column 3, line 49 to column 4, lines 7.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Otsuka and incorporate a third layer. One would be motivated to do so since Otsuka teaches that the composite should contain at least two layers; therefore suggesting the incorporation of more than one polymer layer or macromolecular layer respectively.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Otsuka and Ercillo and manipulate the arrangement of the polymer layers according to the glass temperature of the polymer. One would be motivated to do so since Ercillo teaches the manipulation of the adhesive layers based on the glass temperate yields the desired converting performance and adherence properties.

Conclusion

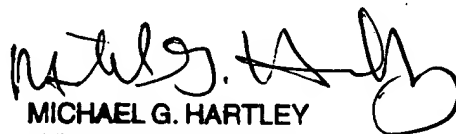
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

June 27, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER

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